

PHARMACY BOARD[657]

Notice of Intended Action

Twenty-five interested persons, a governmental subdivision, an agency or association of 25 or more persons may demand an oral presentation hereon as provided in Iowa Code section 17A.4(1)“b.”

Notice is also given to the public that the Administrative Rules Review Committee may, on its own motion or on written request by any individual or group, review this proposed action under section 17A.8(6) at a regular or special meeting where the public or interested persons may be heard.

Pursuant to the authority of Iowa Code sections 17A.3 and 147.76, the Board of Pharmacy hereby gives Notice of Intended Action to amend Chapter 35, “Contested Cases,” and Chapter 36, “Discipline,” Iowa Administrative Code.

The amendments were approved at the September 28, 2010, regular meeting of the Board of Pharmacy.

The proposed amendments correct the name of the Board by deleting the term “Examiners” and correct the title of the executive director, formerly the executive secretary/director. The proposed amendments also eliminate an invalid Iowa Code reference in Item 20. Proposed amendments in Items 4, 11, 18, and 23 clarify the process for delivery of various documents and communications relating to contested cases and disciplinary actions.

Requests for waiver or variance of the discretionary provisions of these rules will be considered pursuant to 657—Chapter 34.

Any interested person may present written comments, data, views, and arguments on the proposed amendments not later than 4:30 p.m. on November 23, 2010. Such written materials may be sent to Terry Witkowski, Executive Officer, Board of Pharmacy, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688; or by E-mail to terry.witkowski@iowa.gov.

These amendments are intended to implement Iowa Code sections 17A.10 to 17A.23, 124.304, 124B.12, 126.17, 147.76, 155A.6, 155A.12, 155A.13, 155A.13A, 155A.15 to 155A.18, 155A.26, 205.11, 272C.3 to 272C.6, 272C.9, and 272C.10.

The following amendments are proposed.

ITEM 1. Amend rule 657—35.1(17A,124,124B,126,147,155A,205,272C) as follows:

657—35.1(17A,124,124B,126,147,155A,205,272C) Scope and applicability. This chapter applies to contested case proceedings, including licensee, registrant, or permittee discipline, conducted by the board of pharmacy ~~examiners~~.

ITEM 2. Amend rule **657—35.2(17A,272C)**, definition of “Board,” as follows:

“Board” means the Iowa board of pharmacy ~~examiners~~.

ITEM 3. Amend rule **657—35.2(17A,272C)**, definition of “Presiding officer,” as follows:

“Presiding officer” means members of the board of pharmacy ~~examiners~~, or the administrative law judge assigned to preside over the case pursuant to rule 657—35.6(17A,272C).

ITEM 4. Amend subrule 35.5(1) as follows:

35.5(1) Delivery. Delivery of the notice of hearing constitutes the commencement of the contested case proceeding. To the degree practicable, the board shall select the procedure for providing written notice that best ensures prompt, reliable delivery. Delivery may be executed by:

- a. ~~Personal service as provided in the Iowa Rules of Civil Procedure; or delivery;~~
- b. Certified mail, return receipt requested, to the last address on file with the board; or
- c. Certified mail to the last address on file with the board;
- ~~e- d.~~ First-class mail to the last address on file with the board; or

e. Facsimile. Facsimile transmission may be used as the sole method of delivery if the party to be served has filed a written request that board communications be sent by facsimile and has provided a facsimile telephone number for that purpose;

f. Other electronic transmission. Other electronic transmission, such as E-mail, may be used as the sole method of delivery if the party to be served has filed a written request that board communications be sent by such other electronic transmission and has provided an address for that purpose; or

g. Publication, as provided in the Iowa Rules of Civil Procedure.

ITEM 5. Amend rule 657—35.6(17A,272C) as follows:

657—35.6(17A,272C) Presiding officer for nondisciplinary hearings.

35.6(1) *Request for administrative law judge.* Any party may request that an administrative law judge employed by the department of inspections and appeals be assigned to render a proposed decision in a nondisciplinary hearing. The written request shall be filed with the executive ~~secretary/director~~ director within 20 days after service of a notice of hearing identifying or describing the presiding officer as the members of the board.

35.6(2) *Grounds for denial.* The executive ~~secretary/director~~ director may deny the request only upon a finding that one or more of the following apply:

a. to h. No change.

35.6(3) *Written ruling.* The executive ~~secretary/director~~ director shall issue a written ruling specifying the grounds for the decision within 20 days after a request for an administrative law judge is filed.

35.6(4) and **35.6(5)** No change.

ITEM 6. Amend subrule 35.11(3) as follows:

35.11(3) *Filing—when required.* After the notice of hearing, all pleadings, motions, documents or other papers in a contested case proceeding shall be filed with the Iowa Board of Pharmacy ~~Examiners~~, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688. All pleadings, motions, documents or other papers that are required to be served upon a party shall be filed simultaneously with the board of ~~pharmacy examiners~~.

ITEM 7. Amend subrule 35.11(5) as follows:

35.11(5) *Proof of mailing.* Proof of mailing includes one of the following:

- a.* A legible United States Postal Service postmark on the envelope;
- b.* A certificate of service;
- c.* A notarized affidavit; or
- d.* A certification in substantially the following form:

I certify under penalty of perjury and pursuant to the laws of Iowa that, on (date of mailing), I mailed copies of (describe document) addressed to the Iowa Board of Pharmacy ~~Examiners~~, 400 S.W. Eighth Street, Suite E, Des Moines, Iowa 50309-4688, and to the names and addresses of the parties listed below by depositing the same in (a United States post office mailbox with correct postage properly affixed or state interoffice mail).

Date

Signature

ITEM 8. Amend rule 657—35.13(17A,272C) as follows:

657—35.13(17A,272C) Subpoenas.

35.13(1) *Issuance of investigatory subpoenas.*

a. The board's executive ~~secretary/director~~ director or designee may, upon the written request of a board investigator or on the executive ~~secretary/director's~~ director's own initiative, subpoena books, papers, records, and other real evidence which the executive ~~secretary/director~~ director determines are necessary for the board to decide whether to institute a contested case proceeding. In the case of

a subpoena for mental health records, each of the following conditions shall be satisfied prior to the issuance of the subpoena:

(1) to (4) No change.

b. A written request for a subpoena or the executive ~~secretary/director's~~ director's written memorandum in support of the issuance of a subpoena shall contain the following:

(1) to (4) No change.

c. Each subpoena shall contain:

(1) to (4) No change.

(5) The signature, address and telephone number of the executive ~~secretary/director~~ director or designee;

(6) and (7) No change.

d. to g. No change.

35.13(2) Issuance of subpoenas in a contested case.

a. Subpoenas issued in a contested case may compel the attendance of witnesses at depositions or hearing, and may compel the production of books, papers, records, and other real evidence. A command to produce evidence or to permit inspection may be joined with a command to appear at deposition or hearing, or may be issued separately. Upon written request, the executive ~~secretary/director~~ director or designee shall issue subpoenas. A request for a subpoena of patient records must confirm the conditions described in subrule 35.13(1), paragraph "a," prior to the issuance of the subpoena.

b. No change.

c. Each subpoena shall contain, as applicable:

(1) to (8) No change.

(9) The signature, address, and telephone number of the executive ~~secretary/director~~ director or designee;

(10) and (11) No change.

d. Unless a subpoena is requested to compel testimony or documents for rebuttal or impeachment purposes, the executive ~~secretary/director~~ director or designee shall mail copies of all subpoenas to the parties to the contested case. The person who requested the subpoena is responsible for serving the subpoena upon the subject of the subpoena.

e. to h. No change.

35.13(3) No change.

ITEM 9. Amend subrule 35.15(1) as follows:

35.15(1) Request or order for conference. Any party may request a prehearing conference. A written request for prehearing conference or an order for prehearing conference on the presiding officer's own motion shall be filed not less than seven days prior to the hearing date. A prehearing conference shall be scheduled not less than three business days prior to the hearing date.

Written notice of the prehearing conference shall be given by the executive ~~secretary/director~~ director to all parties. For good cause the presiding officer may permit variances from this rule.

ITEM 10. Amend rule 657—35.16(17A,272C) as follows:

657—35.16(17A,272C) Continuances. Unless otherwise provided, applications for continuances shall be made to the presiding officer or, in the case of a ~~license~~ licensee or registrant disciplinary hearing, to the executive ~~secretary/director~~ director.

35.16(1) Requirements of application. A written application for a continuance shall:

a. to c. No change.

An oral application for a continuance may be made if the presiding officer, or in a disciplinary hearing the executive ~~secretary/director~~ director, waives the requirement for a written motion. However, a party making such an oral application for a continuance must confirm that request by written application within five days after the oral request unless that requirement is waived by the presiding officer or, in a disciplinary hearing, by the executive ~~secretary/director~~ director. No application for continuance shall

be made or granted without notice to all parties except in an emergency where notice is not feasible. The board may waive notice of such requests for a particular case or an entire class of cases.

35.16(2) Consideration of application. In determining whether to grant a continuance, the presiding officer, or in a disciplinary hearing the executive ~~secretary/director~~ director, may consider:

a. to i. No change.

The presiding officer, or in a disciplinary hearing the executive ~~secretary/director~~ director, may require documentation of any grounds for continuance.

ITEM 11. Amend paragraph **35.19(9)“d”** as follows:

d. Be delivered to the licensee, permittee, or registrant ~~by personal service or by certified mail, return receipt requested by one of the methods provided for in subrule 35.5(1).~~

ITEM 12. Amend subrule 35.22(6) as follows:

35.22(6) Others authorized to communicate with presiding officer. The executive ~~secretary/director~~ director or other persons may be present in deliberations or otherwise advise the presiding officer without notice or opportunity for parties to participate as long as they are not disqualified from participating in the making of a proposed or final decision under any provision of law and they comply with subrule 35.22(1).

ITEM 13. Amend subrule 35.22(10) as follows:

35.22(10) Sanctions for violation. The presiding officer may render a proposed or final decision imposing appropriate sanctions for violations of this rule, including default, a decision against the offending party, censure, or suspension or revocation of the privilege to practice before the board. Violation of ex parte communication prohibitions by board personnel shall be reported to the executive ~~secretary/director~~ director for possible sanctions including censure, suspension, dismissal, or other disciplinary action.

ITEM 14. Amend subrule 35.26(5) as follows:

35.26(5) Scheduling. The board of ~~pharmacy examiners~~ shall issue a schedule for consideration of the appeal.

ITEM 15. Amend subrule 35.27(3) as follows:

35.27(3) Time of filing. The application shall be filed with the board of ~~pharmacy examiners~~ within 20 days after issuance of the final decision.

ITEM 16. Amend subrule 35.27(4) as follows:

35.27(4) Notice to other parties. A copy of the application shall be timely mailed by the applicant to all parties of record not joining therein. If the application does not contain a certificate of service, the board of ~~pharmacy examiners~~ shall serve copies on all parties.

ITEM 17. Amend subrule 35.28(1) as follows:

35.28(1) When available.

a. Any party to a contested case proceeding may petition the board of ~~pharmacy examiners~~ for a stay of an order issued in that proceeding or for other temporary remedies, pending review by the board. The petition shall be filed with the notice of appeal and shall state the reasons justifying a stay or other temporary remedy. The board may rule on the stay or authorize the presiding officer to do so.

b. Any party to a contested case proceeding may petition the board of ~~pharmacy examiners~~ for a stay or other temporary remedies, pending judicial review of all or part of that proceeding. The petition shall state the reasons justifying a stay or other temporary remedy.

ITEM 18. Amend subrule 35.30(2) as follows:

35.30(2) Issuance of order.

a. No change.

b. The written emergency adjudicative order shall be immediately delivered to persons who are required to comply with the order by utilizing one or more of the following procedures:

(1) Personal delivery;

(2) Certified mail, return receipt requested, to the last address on file with the board;

- (3) Certified mail to the last address on file with the board;
- (4) First-class mail to the last address on file with the board; ~~or~~
- (5) Facsimile. Facsimile transmission may be used as the sole method of delivery if the person required to comply with the order has filed a written request that board orders be sent by facsimile and has provided a facsimile telephone number for that purpose; or

(6) Other electronic transmission. Other electronic transmission, such as E-mail, may be used as the sole method of delivery if the party to be served has filed a written request that board communications be sent by such other electronic transmission and has provided an address for that purpose.

c. No change.

ITEM 19. Amend subrule 36.2(5) as follows:

36.2(5) *Investigation of allegations.* In order to determine if probable cause exists for a disciplinary hearing, the board, the executive ~~secretary/director~~ director, or someone designated by the executive ~~secretary/director~~ director shall cause an investigation to be made into the allegations of the complaint. The licensee, registrant, or permittee ~~complained of~~ who is the subject of the complaint shall be given the opportunity to present to the investigator a position or defense respecting the allegations of the complaint prior to the commencement of a contested case.

ITEM 20. Amend rule 657—36.4(17A,124,124B,126,147,155A,272C) as follows:

657—36.4(17A,124,124B,126,147,155A,272C) Disciplinary proceedings. The proceeding for revocation, suspension, or other disciplinary sanctions against a pharmacy license, a wholesale drug license, a pharmacy technician registration, a pharmacy support person registration, a pharmacist-intern registration, or a license to practice pharmacy, or the denial of or refusal to issue or renew a license or registration, or the suspension, denial, or revocation of a permit to handle precursor substances shall be substantially in accordance with the procedures set forth in 657—Chapter 35 and these rules, which are in addition to the procedures stated in Iowa Code ~~sections 147.58 et seq., and~~ chapter 17A and Iowa Code section 155A.16.

ITEM 21. Amend subrule 36.5(1) as follows:

36.5(1) *Preparation of notice.* The executive ~~secretary/director~~ director shall prepare the notice of hearing upon direction to do so by the board upon a probable cause determination.

ITEM 22. Amend paragraph **36.6(1)“b”** as follows:

b. The board chairperson may designate the executive ~~secretary/director~~ director or one or more board members with authority to negotiate on behalf of the board.

ITEM 23. Amend rule 657—36.10(17A,272C) as follows:

657—36.10(17A,272C) Notification of decision. All parties to a proceeding hereunder shall be promptly furnished with a copy of any final decision or order ~~either in person or by first-class mail by one of the methods provided for in 657—subrule 35.5(1),~~ or by telephone if necessary to ensure that the parties learn of the decision or order first.

ITEM 24. Amend subrule 36.14(1) as follows:

36.14(1) *Request.* Upon written request of the respondent and approval by the executive ~~secretary/director~~ director of the board, an informal reinstatement conference may be held before the board.

ITEM 25. Amend subrule 36.18(3) as follows:

36.18(3) *Fees, costs are part of disciplinary order.* Fees and costs assessed by the board pursuant to subrule 36.18(2) shall be calculated by the board’s executive ~~secretary/director~~ director and shall be entered as part of the board’s final disciplinary order. The board’s final disciplinary order shall specify the time period in which the licensee or registrant shall pay the assessed fees and costs.